

REMARKS

This Amendment is submitted in reply to the final Office Action mailed on December 9, 2009. The Office Action provided a three-month shortened statutory period in which to respond, ending on March 1, 2010. Accordingly, this amendment is timely submitted. No fee is believed due in connection with this Amendment. The Director is authorized to charge any additional fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Applicant has fully considered the Office Action and cited references and submits this Reply and Amendment in response to the outstanding rejections. Reconsideration of the application for patent is requested. Applicant does not acquiesce in the correctness of the rejections or objections and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Claims 1-2, 5 and 8-15 are pending in this application. Claims 3-4 and 6-7 were previously canceled. In the Office Action, Claims 1-2, 5 and 8-15 are rejected under 35 U.S.C. §103. In response, Claims 1 and 10-15 have been amended and Claim 5 has been canceled without prejudice or disclaimer. The amendments do not add new matter and are supported in the specification at, for example, page 4, line 7-page 5, line 2. In view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the rejection should be withdrawn.

In the Office Action, Claims 1-2, 5 and 8-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 02/39834 to Spivey-Krobath et al. ("*Spivey-Krobath*") in view of U.S. Patent No. 6,489,310 to Brassart et al. ("*Brassart*"). Applicant respectfully disagrees with and traverses the rejection for at least the reasons set forth below.

Independent Claims 1 and 10-15 recite, in part, a nutritional composition comprising 4.5 to 6g protein/100ml composition. Independent Claims 1 and 10-15 further recite, in part, a dietary fiber comprising 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligosaccharides. In addition, independent Claims 1 and 10-15

recite, in part, that the composition comprises a viscosity of 30 – 80 mPas. In contrast, Applicant respectfully submits that the cited references alone or in combination fail to disclose or suggest every element of independent Claims 1 and 10-15.

Malnutrition or gastro-intestinal disorders, more generally gut-discomfort or pain, may simply be the consequence of unhealthy or unbalanced nutritional behavior. However, malnutrition may also affect perfectly healthy people, be it due to increased energy expenditure, as is the case with athletes or other sportsmen following intensive physical exercise, be it in other circumstances such as pregnancy. The occurrence of malnutrition in various situations during life, in particular with elderly or ill people, has thus led mainly to high calorie and high nutrient compositions. Consumption of such compositions, however, was often problematic, especially in patients with unbalanced gut flora and with gut impairment, because of gut pain or discomfort. See, specification, page 1, line 20-page 3, line 6.

Applicant submits herewith a Declaration under 37 C.F.R. §1.132 (“*Declaration*” attached hereto as Exhibit A) that demonstrates the nonobviousness of the claimed invention with respect to the prior art. Specifically, the *Declaration* summarizes a controlled study performed by Applicant that demonstrates the surprising and unexpected tolerability of a composition having an increased amount of fiber that is nearly identical to the presently claimed composition as compared to a similar composition having a lower amount of fiber. As is demonstrated by the study discussed in Exhibit B of the *Declaration*, the presently claimed compositions have been found not to promote any undesired abdominal symptoms due to the increased amount of fiber. Indeed, the study discussed in the *Declaration* demonstrates that presently claimed low viscosity, high fiber compositions resulted in clinical compliance similar to that of a similar, non-fiber product and is equally well tolerated.

As supported in the *Declaration*, Applicant has surprisingly found that a nutritional composition including 4.5 to 6g protein/100ml composition and acacia gum as a soluble fiber in addition to pea outer fiber and fructooligosaccharides demonstrated good shelf-stability for 8 months and was judged to have a good taste. See, specification, Example at pages 12-15. The composition was rich in fiber and improved intestinal transit, gut flora and gut comfort. See, specification, Example, pages 12-15. Accordingly, the claimed invention provides a nutritional

composition that has a high energy content and improves digestive tract health. The presently claimed compositions also provide the advantage of a surprisingly low viscosity that results from use of the claimed fiber blend. As discussed in the *Declaration*, despite the high proportion of soluble non-starch polysaccharides and oligosaccharides, and the high amount of total fiber of the compositions, the compositions have a surprisingly low viscosity and are surprisingly well tolerated.

Further, the *Declaration* also describes the synergistic effect that is surprisingly observed between fructooligosaccharides and acacia gum on the bifidogenic effect. As is described in detail in the *Declaration* at Exhibit E, using blends of fructooligosaccharides and acacia gum, an effective dose of prebiotic can be optimized in order to reduce potential abdominal discomfort related to the intake of fructooligosaccharides. Accordingly, not only does the *Declaration* demonstrate that the present compositions are as well tolerated as a similar, non-fiber composition, but the *Declaration* also demonstrates that using blends of fructooligosaccharides and acacia gum further reduces potential abdominal discomfort typically associate with the intake of fructooligosaccharides.

Spivey-Krobath and *Brassart* alone or in combination fail to disclose or suggest a nutritional composition comprising 4.5 to 6g protein/100ml composition as required by independent Claims 1 and 10-15. *Spivey-Krobath* and *Brassart* alone or in combination also fail to disclose or suggest a source of dietary fiber comprising a specific blend of 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligosaccharides. Finally, *Spivey-Krobath* and *Brassart* alone or in combination fail to disclose or suggest that the nutritional composition comprises a viscosity of 30 – 80 mPas as required by independent Claims 1 and 10-15.

Spivey-Krobath is primarily directed toward a nutritional composition for the prevention or treatment of an immune condition. The only reference to specific amounts of protein at any place in *Spivey-Krobath* is in Table 1 on page 10 where it is specified that the composition contains either 10.5 or 7.0 g protein/100ml of composition dependent on the desired energy content of the composition, which falls outside the claimed range. See, *Spivey-Krobath*, Table 1. Further, *Spivey-Krobath* also fails to teach or suggest any viscosity for its nutritional

composition. Moreover, *Spivey-Krobath* fails to teach the use of pea outer fiber. As such, *Spivey-Krobath* fails to disclose or suggest the specific combination of dietary fiber that comprises 20-40% by weight acacia gum, 30-60% by weight of pea outer fiber and 20-40% by weight of fructooligosaccharides to provide a composition having a viscosity of 30 – 80 mPas in accordance with the present claims.

Brassart is entirely directed toward an enteral composition that contains a protein source, a lipid source, a carbohydrate source and a fiber blend. See, *Brassart*, Abstract. However, the only place in the disclosure of *Brassart* that discusses specific amounts of protein are in the examples, where 3.8g protein/100ml composition was used, which is below the claimed range. See, e.g., *Brassart*, Example 1. Further, *Brassart* fails to disclose or suggest the presently claimed viscosity of the composition. Instead, *Brassart* discloses that its enteral composition may have a viscosity of less than about 12 cp at room temperature, which is outside the claimed range. See, *Brassart*, column 6, lines 40-44. Finally, *Brassart* fails to teach or suggest the use of acacia gum and therefore is deficient with respect to the claimed source of dietary fiber.

Applicant respectfully submits that *Spivey-Krobath* clearly does not disclose the “identical” composition to that presently claimed. Instead, as Applicant has already pointed out, *Spivey-Krobath* and *Brassart* fail to disclose the presently claimed compositions having certain protein and fibers amounts. Of course, the amount of components contained in a composition can greatly affect the viscosity of the composition. Because the cited references fail to disclose or suggest each and every element of the present claims, Applicant respectfully submits that it is improper for the Patent Office to allege that the compositions of the cited references have viscosity ranges that are “identical” to the viscosities of the claimed compositions.

In addition, to satisfy the test for inherency, the Patent Office would be required to show that the compositions of *Spivey-Krobath* and *Brassart* necessarily (i.e., always or automatically) provide for compositions having a viscosity of about 30-80 mPas. That condition simply is not met under the present circumstances, especially in view of the fact that the claimed nutritional compositions and compositions of the cited references are not the same. For example, neither *Spivey-Krobath* and *Brassart* teach the specific dietary fiber blends in accordance with the present claims. The fact that a certain result or characteristic may occur or be present in the prior

art is not sufficient to establish the inherency of that result or characteristic. See, MPEP 2112. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

Applicant respectfully submits that the Patent Office has improperly applied hindsight reasoning by selectively piecing together teachings of each of the references in an attempt to recreate what the claimed invention discloses. As the Federal Circuit explained, “the mere fact that the prior art may be modified in the manner suggested by the examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.” *In re Fritch*, at 1783-17. The claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983); *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995).

In sum, the cited references alone or in combination fail to disclose or suggest each and every element of independent Claims 1 and 10-15. Moreover, the cited references fail to even recognize the advantages, unexpected benefits and/or properties of nutritional product in accordance with the present claims and as described in detail in the attached Exhibits. For at least the reasons discussed above, Applicant respectfully submits that independent Claims 1 and 10-15, along with the claims that depend from Claims 1 and 10-15, are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicant respectfully requests that the obviousness rejection of the pending claims under 35 U.S.C. §103(a) be reconsidered and withdrawn.

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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Attachments: Exhibits A-E